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EXAMINER

SINES, BRIAN J

ART UNIT PAPER NUMBER

1743

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/895,945

Applicant(s)

FRANK ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43-45, 47 and 48 is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 19, 21-25, 27-42, 46, 49-77, 79 and 84 is/are rejected.
- 7) ☒ Claim(s) 17, 20, 26, 69-71, 73, 74, 78 and 80-83 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 31, 32, 35, 36, 46 and 49 – 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: It is unclear as to how the electrical feed couples or is connected to the library of samples. Are there sensors in contact with the samples?

Claim 31 recites the limitation "electric motor" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The term "low thermal conductivity" in claim 35 is a relative term which renders the claim indefinite. The term " low thermal conductivity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural

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cooperative relationships are: It is unclear as to how the second data gathering device is coupled or connected to the library of samples. Are there sensors in contact with the samples?

Claim 49 recites the limitation "said housing" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim 53 recites the limitation "first data gathering device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 54 recites the limitation "first data gathering device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 67 – 74 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Regarding claim 67, the claim recites that the method is for screening the material properties or characteristics of one or more material samples. However, there is no screening step recited in the claim. Therefore, the method is incomplete.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

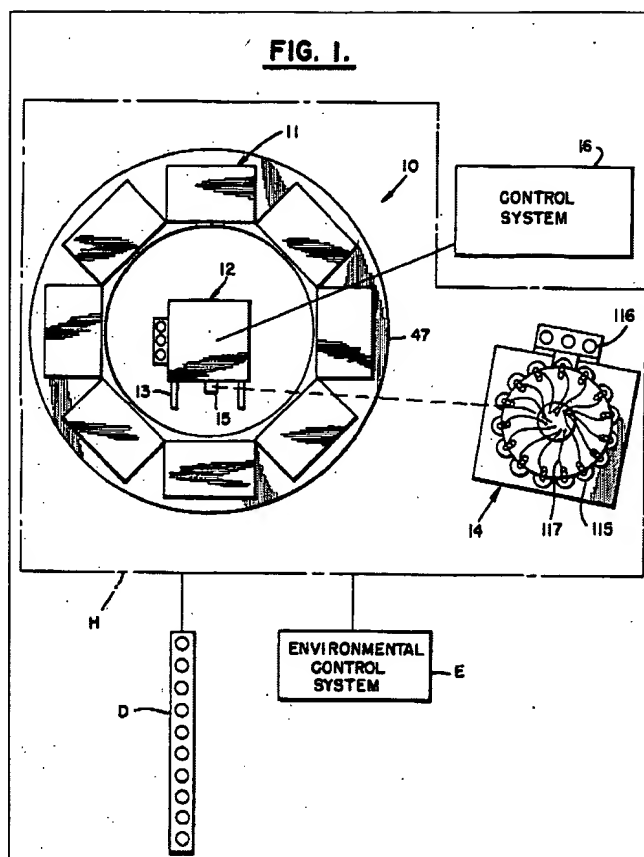
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 6, 8 – 14, 16, 18, 19, 24, 25, 27, 29 – 34, 37, 42, 66 – 68, 72, 75 – 77, 79 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Armes *et al.* (U.S. Pat. No. 4,676,951). Regarding claim 1, Armes *et al.* teach an apparatus 10 comprising: a reaction chamber (tray support tower 11 contained within housing H and further including base frame 54)

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for receiving two or more samples; an injection module (reagent delivery system 14, which includes remote dispensing head 15) in fluid communication with the reaction chamber for permitting *in situ* injection; and a selectively movable transport assembly (selectively operable tray moving means 13) for transporting samples between the reaction chamber and the injection module (see col. 6, lines 1 – 68; col. 7, lines 1 – 6; figures 1 & 7). Regarding claim 2, the selectively movable transport (13) assembly is supported by a portion of the reaction chamber (*e.g.*, the base frame 54 of the housing H) (see figures 1 & 7). Regarding claim 3, the reaction chamber is defined by the interior surfaces of one or more housings (*e.g.*, housing H) (see figure 1). Regarding claim 4, Armes *et al.* teach that the housing H preferably surrounds and encloses the environmentally sensitive elements of the automatic scanning system 10 (see col. 6, lines 32 – 60; col. 7, lines 57 – 65; col. 13, lines 23 – 38).



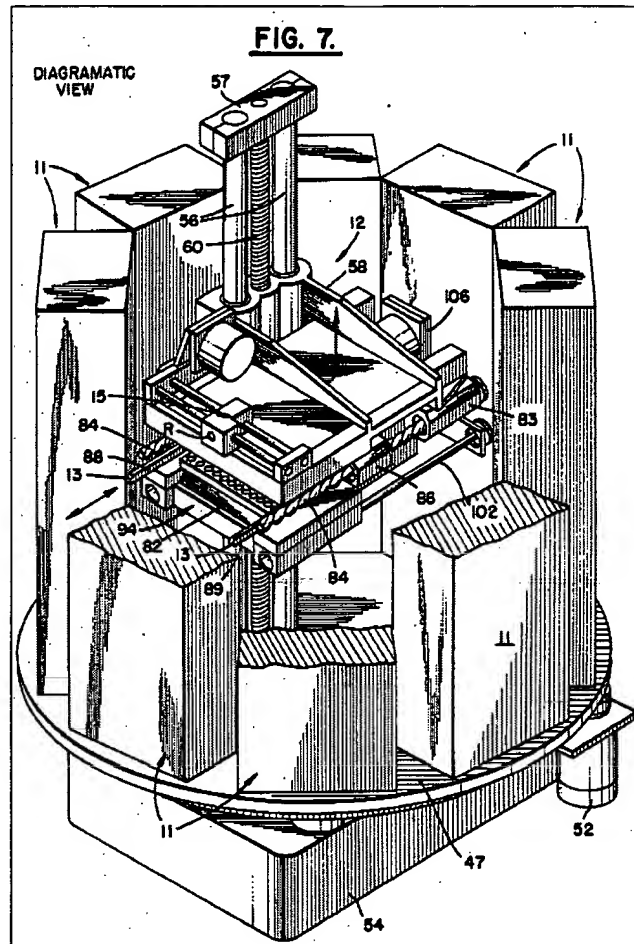
Regarding claims 5, 6, 13, 24, 27, 42 and 66, it should be noted that these claims are directed to an apparatus. Therefore, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus. These claims recite various process or use limitations and are accorded no patentable weight to an apparatus. For example, these claims recite how the apparatus is to be operated, such as in a pressurized mode of operation using a charging reagent, which do not impart any limitations to define the structure of the apparatus being claimed. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention. If the prior art structure is

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capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Regarding claims 8 and 9, the apparatus further comprises a selectively movable plate (the carousel 47 comprises a donut-shaped plate, which surrounds the work station 12), which is supported in the reaction chamber (see col. 9, lines 14 – 45; figures 1 & 7). Regarding claim 9, the carousel 47 supports tray towers 11, which define one or more slots for retaining the samples in trays 18 (see figures 2 & 7). Regarding claim 10, a spacer plate (carrier frame 58) is mounted in the reaction chamber for adjusting the volume of space below plate 58 (see figure 7). Regarding claim 11, a spacer plate (carrier frame 58) is mounted in the reaction chamber for adjusting the volume of space above plate 47 (see figure 7). Regarding claims 12 and 13, the injection module 14 comprises an injection manifold 15 (see col. 6, lines 1 – 60). Regarding claim 14, *Armes et al.* teach the incorporation of syringe pumps 115 for delivering reagents (see col. 14, lines 6 – 63). Regarding claim 16, the injection module 14 is supported by a selectively movable surface (carriage 138) (see col. 15, lines 9 – 22; figure 15). Regarding claim 18, *Armes et al.* teach the incorporation of a workstation 12 for sample analysis (see col. 13, lines 1 – 22). *Armes et al.* further teach the use of electrical impedance in monitoring samples (see col. 3, lines 12 – 21). Regarding claim 19, *Armes et al.* teach the incorporation of an optical detection system for sample analysis (see col. 3, lines 41 – 64; col. 6, lines 61 – 63; col. 13, lines 5 – 68 & col. 14, lines 1 – 5). Regarding claims 25 and 27, the data gathering device 12 is supported by the apparatus on base frame 54 (see figure 7). Regarding claims 29, 30 and 33, the transport assembly 13 comprises: a selectively movable carriage 86; a support member 58 upon which the carriage rests; and a drive system (*e.g.*, drive pulleys 90, cogged belt 91 & stepper motor 93 &

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66) (see col. 10, lines 35 – 62; figure 7). Regarding claims 31 and 32, Armes *et al.* teach the incorporation of a threaded drive screw 60 in the drive system (see col. 9, lines 46 – 66; figure 7). Regarding claim 34, Armes *et al.* teach the incorporation of two elongated rods (a pair of vertical shafts 56) as support members (see col. 9, lines 46 – 66; figure 7). Regarding claim 37, the samples comprising the libraries are retained on a sample plate (container tray 18) (see col. 7, lines 7 – 56). Regarding claim 42, the one or more samples comprising the library may be retained in separate wells or cuvettes supported on a common substrate comprising the container tray 18 (see col. 8, lines 3 – 37). Regarding claims 67, 75, 77 and 79, Armes *et al.* teach a method comprising the steps of: providing a reaction chamber (tray support tower 11 contained within housing H and further including base frame 54); loading one or more sample plates (container tray 18) into the reaction chamber; sealing the reaction chamber; and transporting the sample plates using a selectively movable transport assembly (selectively operable tray moving means 13) to an injection module (reagent delivery system 14, which includes remote dispensing head 15) of the reaction chamber for injection of one or more chemical components into the reaction chamber (see col. 6, lines 1 – 68; col. 7, lines 1 – 6; figures 1 & 7). Regarding claims 68 and 76, the transporting step may be carried out at ambient conditions (see col. 6, lines 1 – 60). Regarding claims 72 and 84, Armes *et al.* teach the use of a work station which incorporates an analyzing means (see col. 6, lines 61 – 65).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armes *et al.* in view of Laugharn, Jr. *et al.* (U.S. Pat. No. 6,036,923 A). Regarding claim 7, Armes *et al.* do not specifically teach the incorporation of a pressure gauge with the reaction chamber. Armes *et al.* do teach that various gauges and indicators may be incorporated into the apparatus (see col. 6, lines 52 – 60). Laugharn, Jr. *et al.* teach a pressure cycling reactor and methods of controlling biological reactions, such as enzymatic reactions, using pressure. Laugharn, Jr. *et al.* teach that the reaction chamber of the apparatus incorporates the use of a pressure gauge, such as a strain gauge type pressure transducer 102 (see col. 19, lines 9 – 12). Hence, Laugharn, Jr. *et al.* recognize the suitability of incorporating the use of a pressure gauge or equivalent pressure measuring device with a reactor for controlling biological reactions (see MPEP § 2144.07). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a pressure gauge with a reactor, as taught by Laugharn, Jr. *et al.*, for use with the apparatus, as taught by Armes *et al.*, in order to provide an effective means of monitoring and controlling the reactor. Regarding claim 28, Laugharn, Jr. *et al.* teach the incorporation of control valves (see col. 17, lines 1 – 67).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Armes *et al.* in view of Miyake *et al.* (U.S. Pat. No. 4,812,392). Regarding claim 15, Armes *et al.* do not specifically teach the incorporation of one or more pneumatic cylinders for facilitating the movement of the selectively movable surface 13 for moving the injection module a predetermined distance. Armes *et al.* teach that the movable surface 13 incorporates the use of a

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tray moving system comprising a tray drive mount 83, which is located at one end of drive screws 84 (see col. 10, lines 35 – 65). Miyake *et al.* teach a method and apparatus for incubating and monitoring cell cultures. Miyake *et al.* teach an apparatus which incorporates the use of pneumatically-operated cylinders 26 in moving a tray support 14 (see col. 4, lines 26 – 58). Miyake *et al.* recognize the suitability of incorporating one or more pneumatic cylinders for the intended purpose of facilitating sample tray movement and transfer (see MPEP § 2144.07). Both of these disclosed technologies, the use of drive screws and pneumatic cylinders, are notoriously well known in the art for being utilized for the same or similar purpose of facilitating sample transfer in an analytical apparatus, as evidenced by Armes *et al.* and Miyake *et al.*, respectively. Hence, these techniques are considered functional equivalents recognized in the prior art (see MPEP section 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Therefore, it would have been obvious to one of ordinary skill in the art to substitute and incorporate the known equivalent technique of using pneumatic cylinders, as taught by Miyake *et al.*, with the apparatus, as taught by Armes *et al.*, in order to facilitate effective apparatus control.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armes *et al.* in view of Trivedi *et al.* (U.S. Pat. No. 3,961,899). Regarding claims 21 and 22, Armes *et al.* do not specifically teach the incorporation of a sample viewing window with the reaction chamber. Trivedi *et al.* teach a reaction container for chemical analysis, wherein the container or reaction chamber comprises a transparent window for facilitating sample analysis (see col. 2, lines 11 – 46). Therefore, it would have been obvious to one of ordinary skill in the art to

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incorporate the use of a window in a reaction chamber, as taught by Trivedi *et al.*, with the apparatus, as taught by Armes *et al.*, in order to facilitate the effective monitoring of the reaction chamber contents.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Armes *et al.* and Trivedi *et al.* as applied to claims 21 and 22 above, and further in view of Loewenstein *et al.* (U.S. Pat. No. 5,101,764 A). Neither Armes *et al.* or Trivedi *et al.* specifically teach the incorporation of a sapphire window. Loewenstein *et al.* do teach the incorporation of an optical window, which is made of sapphire, in a reaction chamber (see col. 3, lines 34 – 66). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate an optical window made of sapphire, as taught by Loewenstein *et al.*, with the apparatus, as taught by Armes *et al.* and Trivedi *et al.*, since the Courts have held that the selection of a known material, based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960).

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armes *et al.* in view of Atwood *et al.* (U.S. Pat. No. 5,710,381 A). Armes *et al.* do not specifically teach that the carriage may be fabricated from a polymeric material. Armes *et al.* do teach that the apparatus is utilized for temperature controlled chemical analysis (see col. 6, lines 32 – 60). However, Atwood *et al.* do teach a holder, which is fabricated from an injection molded polymeric plastic material, for holding sample tubes for use in temperature sensitive chemical analyses, such as PCR (see col. 3, lines 7 – 67). Atwood *et al.* recognize the suitability of utilizing a polymeric material for use in fabricating an apparatus for performing thermally or temperature sensitive chemical analyses (see MPEP § 2144.07). Therefore, it would have been

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obvious to one of ordinary skill in the art to incorporate a polymeric material, as taught by Atwood *et al.*, in the fabrication of the carriage of the apparatus, as taught by Armes *et al.*, since the Courts have held that the selection of a known material, based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960).

Claims 38 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armes *et al.* in view of Maruyama *et al.* (U.S. Pat. No. 4,735,778). Regarding claim 38, Armes *et al.* do not specifically teach that the sample plate may be fabricated from a polymeric material. However, Maruyama *et al.* do teach a microtiter plate, which is fabricated from a copolymer resin, for use in chemical analyses utilizing optical detection methods (see col. 1, lines 1 – 57 & col. 4, lines 21 – 67). Therefore, it would have been obvious to one of ordinary skill in the art to fabricate the sample plate using a polymeric resin, as taught by Maruyama *et al.*, for use with the analysis apparatus, as taught by Armes *et al.*, since the Courts have held that the selection of a known material, based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960). Regarding claim 39, Armes *et al.* teach that the sample plate 18 is supported by a support plate (tray assembly 17) (see col. 8, lines 3 – 68; figure 2). Regarding claim 40, Armes *et al.* teach the incorporation of a top plate 45 and a bottom plate 46 comprising indexing pins or tie-down bolts 34 (see col. 8, lines 3 – 68; col. 9, lines 1 – 13; figure 2). Regarding claim 41, Armes *et al.* teach the incorporation of a registration pocket or shelf 35, upon which each tray assembly 17 rests (see col. 8, lines 24 – 51).

Allowable Subject Matter

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Claims 43 – 45, 47 and 48 are allowed.

Claims 17, 20, 26, 69 – 71, 73, 74, 78 and 80 – 83 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 49 – 65 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter:

Armes et al. teach an automatic analyzing system and method of operating the system.

Regarding claim 17, the cited prior art neither teach or fairly suggest the further incorporation of sensors for disrupting the movement of the movable surface upon detection of unwanted objects in the travel path of the movable surface. Regarding claims 20 and 26, the cited prior art neither teach or fairly suggest the further incorporation of a data gathering device which is an infrared camera. Regarding claim 43, the cited prior art neither teach or fairly suggest a screening apparatus comprising: a first housing having at least a partially open center; and a second housing having at least a partially open center, whereby the partially open center of the first housing and the partially open center of the second housing are adapted for sealing engagement to define a reaction chamber. Regarding claim 49, the cited prior art neither teach or fairly suggest a screening apparatus comprising: a first housing defining fluid inlet ports, wherein the housing has at least one partially open surface; a reaction chamber at least partially defined by a hollow center portion of the first housing, wherein the first housing supports a selectively movable plate in the reaction chamber; a movable transport module supported by the first housing for transferring samples into or out of the reaction chamber; and an injection module

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supported by a second selectively movable housing for *in situ* injection of chemical components onto the samples contained within the reaction chamber, wherein the second housing may be moved into contact with the first housing to seal and enclose the reaction chamber. Regarding claims 69 and 78, the cited prior art neither teach or fairly suggest the further incorporation of pressurizing the reaction chamber with a charging agent. Regarding claim 70, the cited prior art neither teach or fairly suggest the further step of permitting the reaction chamber to come to pressure and temperature equilibrium after introducing the charging agent into the reaction chamber and prior to injecting chemical components into the reaction chamber via the injection module. Regarding claims 71 and 81, the cited prior art neither teach or fairly suggest the further step of injecting the chemical components onto two or more samples. Regarding claim 73, the cited prior art neither teach or fairly suggest the further step of evacuating or purging the reaction chamber. Regarding claims 74 and 83, the cited prior art neither teach or fairly suggest the further step of using an infrared camera for analysis.

Conclusion

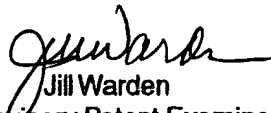
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Margrey *et al.* teach a robotically operated laboratory system. Nardo teaches an analyzer using a circular plate for presenting samples for densitometric analysis. Thorne *et al.* teach an automatic analyzer using a transport shuttle system. Stevens teaches an analytical apparatus using two moving trains of sample holder-carrying trays.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (703) 305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700